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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,970	04/15/2004	Scott J. Gerondale	3011	7529

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
05/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,970	GERONDALE ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on 3/9/2007.

2. In the reply, the applicant amended claims 1, 4, 6; cancelled claim 7; and added claim 9.

3. Additionally, the applicant amended the specification to obviate the previous objection to the drawings and specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Butuzov et al (5891106). Butuzov et al discloses a controlled volume injection/aspiration device comprising: a syringe having a body (17), needle (12), and piston (18); a shell (2) receiving the syringe; a plunger rack (4; Fig 1) slidably disposed within said shell; a manually operated control (7, Fig 2) disposed in an operative parallel relationship with said plunger rack (Fig 2-3; and see Discussion in Response to Arguments) and slidable there along (Fig 2-3; and see Discussion in Response to Arguments), for moving said plunger rack in a stepwise forward direction causing piston to eject discrete doses of medication (Fig 2-3; Summary, col 4, lns 21-col 5, lns 39) and in a stepwise reverse direction causing piston to aspirate discrete quantities of fluid (Fig

2-3; Summary; col 4, lns 21-col 5, lns 39; col 2, lns 14-19); a window (20; Fig 2) for view aspirated fluid; the control comprising an injecting pawl (5; Fig 2-3; Summary, col 4, lns 21-col 5, lns 39) that engages the plunger rack in a stepwise forward direction and disengages the rack upon movement in a stepwise reverse direction; the control comprising a withdrawing pawl (6; Fig 2-3; Summary, col 4, lns 21-col 5, lns 39) that engages the plunger rack in a stepwise reverse direction and disengages the rack upon movement in a stepwise forward direction; a finger accessible button attached to the control and extending exterior to said shell (7; wherein the grooved tip of 7 farthest from the attachment to (1) is fully capable of being a finger accessible button; see Fig 1); the control being configured for finger operation (Fig 2-3); and the syringe being removable from the shell (col 5, lns 28-39).

6. In reference to claim 9, Butuzov et al additionally discloses a plunger rack (4) slidably disposed within said shell for moving said piston; a control rod (7) disposed in a parallel relationship with said plunger rack, and slidably therealong (Fig 2-3; and see Discussion in Response to Arguments); an injecting pawl (5), pivotably mounted to an end of said control rod, for engaging said plunger rack for moving said plunger rack in a forward direction upon forward movement of said control rod and disengaging said plunger rack upon movement of said control rod in a reverse direction (5; Fig 2-3; Summary, col 4, lns 21-col 5, lns 39); a withdrawing pawl (6; Fig 2-3; Summary, col 4, lns 21-col 5, lns 39) for engaging the control rod end and further engaging said plunger rack for moving said plunger rack each in a reverse direction and disengaging said plunger each upon movement in said forward direction; and a finger accessible button

(7; wherein the grooved tip of 7 farthest from the attachment to (1) is fully capable of being a finger accessible button; see Fig 1); the control being configured for finger operation (Fig 2-3) attached to the control rod and extending exterior to said shell for causing sliding movement of the control rod.

7. Claims 1-4, 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Strum et al (4099548). Strum et al discloses a controlled volume injection/aspiration device comprising: a syringe having a body (Fig 1), needle (35), and piston (33); a shell (11) receiving the syringe; a plunger rack (41, 43) slidably disposed within said shell; a manually operated control (53) disposed in an operative parallel relationship with said plunger rack (53, 61, 69, 51; Figs 1-22) and slidable there along, for moving said plunger rack in a stepwise forward direction causing piston to eject discrete doses of medication (Figs 1-22; Summary; col 2, lns 39-col 4, lns 25) and in a stepwise reverse direction causing piston to aspirate discrete quantities of fluid (Figs 1-22; Summary, col 4, lns 26-col 4, lns 58; col 6, lns 34-46); a window (31) for view aspirated fluid; the control comprising an injecting pawl (49) that engages the plunger rack in a stepwise forward direction and disengages the rack upon movement in a stepwise reverse direction; the control comprising a withdrawing pawl (25, 108, 97; Figs 1-22; col 4, lns 26-col 4, lns 58; col 6, lns 34-46) that engages the plunger rack in a stepwise reverse direction and disengages the rack upon movement in a stepwise forward direction; a finger accessible button attached to the control and extending exterior to said shell (19);

the control being configured for finger operation (Figs 1-22, summary); and the syringe being removable from the shell (Figs 1-22; Summary).

8. In reference to claim 9, Sturm et al additionally discloses a plunger rack (41, 43) slidably disposed within said shell for moving said piston; a control rod (53) disposed in a parallel relationship with said plunger rack, and slidably therealong (Figs 1-22; Summary); an injecting pawl (49), pivotably mounted to an end of said control rod, for engaging said plunger rack for moving said plunger rack in a forward direction upon forward movement of said control rod and disengaging said plunger rack upon movement of said control rod in a reverse direction (49; Figs 1-22; Summary, col 4, lns 26-col 4, lns 58; col 6, lns 34-46); a withdrawing pawl (25, 108, 97; Figs 1-22; col 4, lns 26-col 4, lns 58; col 6, lns 34-46) for engaging the control rod end and further engaging said plunger rack for moving said plunger rack each in a reverse direction and disengaging said plunger each upon movement in said forward direction; and a finger accessible button (19) attached to the control rod and extending exterior to said shell for causing sliding movement of the control rod.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butuzov et al. Butuzov et al discloses the invention substantially as claimed except for expressly disclosing the control is configured to ejecting medicament in the range between 5 microliters and 1 milliliter. Butuzov et al is silent as to then exact medicament dosage injected/withdrawn for each prawl. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control as taught by Butuzov et al with a capability range between 5 microliters and 1 milliliter since it was well known in the art that injection amounts of analgesia is used to provide injection amounts on a drop by drop basis that corresponds to a range between 5 microliters and 1 milliliter because the exact dosage is extremely important to prevent overdosing (col 1, lns 22-53).

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strum et al. Strum et al discloses the invention substantially as claimed except for expressly disclosing the control is configured to ejecting medicament in the range between 5 microliters and 1 milliliter. Strum et al is silent as to then exact medicament dosage injected/withdrawn for each prawl. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control as taught by Strum et al with a capability range between 5 microliters and 1 milliliter since it was well known in the art that injection by hypodermic syringes are often used to provide injection amounts on a drop by drop basis that corresponds to a range between 5 microliters and 1 milliliter because with many medicaments the proper dosage is extremely important to prevent overdosing.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Butuzov et al in view of Pasricha et al (5674205). Butuzov et al discloses the invention substantially as claimed except for expressly disclosing the medicament is BOTOX. Pasricha et al teaches that it is known to have the medicament be BOTOX for the purpose of injecting a neurotoxin, such as BOTOX, to inhibit neurotransmitter release from nerve terminals to treat and alleviate symptoms of certain diseases, such as those arising from chronic smooth muscle disorders. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medicament as taught by Butuzov et al with the BOTOX as taught by Pasricha et al for the purpose of injecting a neurotoxin, such as BOTOX, to inhibit neurotransmitter release from nerve terminals to treat and alleviate symptoms of certain diseases, such as those arising from chronic smooth muscle disorders.

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strum et al in view of Pasricha et al (5674205). Strum et al discloses the invention substantially as claimed except for expressly disclosing the medicament is BOTOX. Pasricha et al teaches that it is known to have the medicament be BOTOX for the purpose of injecting a neurotoxin, such as BOTOX, to inhibit neurotransmitter release from nerve terminals to treat and alleviate symptoms of certain diseases, such as those arising from chronic smooth muscle disorders. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medicament as taught by Strum et al with the BOTOX as taught by Pasricha et al for the purpose of injecting a neurotoxin, such as BOTOX, to inhibit neurotransmitter release from nerve terminals to treat and

alleviate symptoms of certain diseases, such as those arising from chronic smooth muscle disorders.

Response to Arguments

14. Applicant's arguments filed 3/9/2007 have been fully considered but they are not persuasive.

i. The Applicant argues that the limitation of the control rod being disposed in an operative parallel relationship with the plunger rack and being slidable therealong overcomes the rejection by Butuzov et al. (Remarks pg 10, paragraphs 1-2)

15. In response to applicant's argument (i) the Examiner notes that the Applicant has not structurally defined the parallel relationship with respect to axis's or structure. The control rod (7) of Butuzov et al is in the *same longitudinal direction* as the plunger rack (4) and thus has a parallel relationship to the plunger rack. Furthermore, the plunger relationship can be termed to be an operative parallel relationship because during use the control rod maintains constant parallel longitudinal alignment with the plunger rack. The Examiner suggests further defining the operative parallel relationship to include axis's and structure of the interrelatedness of the control rod and the plunger rack with respect to each other.

16. Additionally, the Examiner notes that the Applicant never structurally defines the manner in control rod slides therealong. The Examiner has interpreted the claim language of the control rod being slidable therealong the plunger rack to merely include that the control rod and the plunger rack are slidably moveable with respect to each

other. That is, the control rod actuating the plunger rack and moving the plunger rack distally/proximally constitutes slidable movement therealong the plunger rack by the control rod. The Examiner suggests that the Applicant further define the slidable movement of the control rack with respect to the plunger rack and additionally to the shell housing the syringe.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6007515; 5807340; 6102895; 6159161; 5378233; 1718596; 854399; 780147.

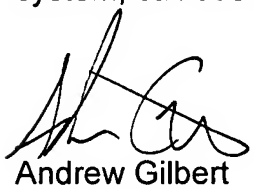
18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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